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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/726,826 | 12/03/2003 | Andrew Thomas Forsberg | 47563.0017 | 5521 |

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| EXAMINER | |
|---|---|
| SEVERSON, RYAN J | |
| **ART UNIT** | **PAPER NUMBER** |
| 3731 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/726,826 | FORSBERG ET AL. | |
| | Examiner | Art Unit | |
| | Ryan Severson | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-39,41,42,44-49,51-55,57-71,73,76 and 77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39,41,42,44-49,51-55,57-71,73,76 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 35-39, 41, 42, 55 and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) in view of Bonutti (2001/0002440) and Bonutti (5,814,073).** Nash et al. disclose the method substantially as claimed, including providing a device with a carrier tube (102), filament (34), insertion sheath (104), anchor (32), and sealing plug (30) wherein the anchor is seated in a multilevel nest or recess (see figure 1). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The tissue puncture is in a blood vessel (see figure 3). The anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

3. However, Nash et al. do not disclose the carrier tube has a second surface spaced radially inward from the first surface when the anchor is undeployed. Attention is drawn to Bonutti '440, who teaches a carrier (92) has a second surface (106) spaced inward from the first surface that contacts the anchor (see figure 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to have included a second surface on the carrier tube of Nash et al. in the manner taught by Bonutti '440. Such a combination is merely a combination of prior art elements according to known methods to yield predictable results. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

4. Further, the combination of Nash et al. and Bonutti '440 does not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti '073, who teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an introducer sheath with resilient tips as taught by Bonutti '073 with the closure device of the combination of Nash et al. and Bonutti '440 to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Nash et al. state the closure device may be used with any typical introducer sheath (see column 4, lines 24-29). The tip of the insertion sheath would slide into a gap between the anchor and the nest because the tip of the sheath is resilient. The resiliency will cause the tips to conform to the shape it is compressed around, thereby filling the gap of the combination of Nash et al. and Bonutti '440 when that point is reached.

5. **Claims 44-49, 51-54, 63-66, 71, 73, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) in view of Bonutti (5,814,073).** Nash et al. disclose the method substantially as claimed, including providing a device with a carrier tube (102), filament (34), insertion sheath (104), anchor (32), and sealing plug (30) wherein the anchor is seated in a multilevel nest or recess (see figure 1). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The tissue puncture is in a blood vessel (see figure 3). The anchor is moved away from and oriented transverse to the carrier tube (see figure 2). However, Nash et al. do not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti, who teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an introducer sheath with resilient tips as taught by Bonutti reference with the closure device of Nash reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

6. **Claims 67-70 rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (5,282,827) in view of Bonutti (5,814,073).** Kensey et al. disclose the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32', see figures 34 and 35), and a sealing plug (30). The anchor is indented because of the area between the raised cap portions (32b) and the proximal end of the anchor. The indent will cause a gap between the anchor and the carrier tube. The tissue puncture is in a blood vessel (see figures 16-18). The device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3). The anchor is moved away from and oriented transverse to the carrier tube (see figure 22). However, Kensey et al. do not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti, who teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an introducer sheath with resilient tips as taught by Bonutti with the closure device of Kensey et al. to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

### *Response to Arguments*

7. Applicant's arguments with respect to claims 35, 37, 44 and 55 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's arguments with respect to claims 49, 63, 67 and 71 have been fully considered but they are not persuasive. Applicant argues the combination of Nash et al. with Bonutti '073 and Kensey et al. with Bonutti '073 does not disclose the insertion sheath rotating the anchor to a deployed position. However, if the insertion sheath is made with resilient tips as taught by Bonutti '073, the insertion sheath would enter the gap formed between the anchor and the carrier tube and then rotate it to a deployed position. Therefore, the arguments are deemed not persuasive.

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731